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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,660	02/06/2002	Ying Huang	267/156	3273

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EXAMINER	
DIAMOND, ALAN D	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/072,660	HUANG ET AL.
	Examiner	Art Unit
	Alan Diamond	1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed on April 15, 2003 and January 30, 2004 does not fully comply with the requirements of 37 CFR 1.98 because: In the IDS filed April 15, 2003, none of the copies of the three foreign patents in the "FOREIGN PATENT DOCUMENTS" section of the PTO-1449 form were provided to the Office. In the IDS filed January 30, 2004, none of the copies of the foreign patents (total of 11) or the copies of the documents cited in the "OTHER DOCUMENTS" section (total of 15) of the PTO-1449 were provided to the Office. Said information disclosure statements filed on April 15, 2003 and January 30, 2004 state that the above documents were not supplied to the Office because they were cited in a prior parent application for which a claim for priority under 35 USC 120 has been made. However, the instant application does not claim any priority under 35 USC 120. Since the submission appears to be *bona fide*, applicant is given **ONE (1) MONTH** from the date of this notice to supply the above mentioned omissions or corrections in the information disclosure statement. NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 CFR 1.136(a) OR (b). Failure to timely comply with this notice will result in the above mentioned information disclosure statement being placed in the application file with the noncomplying information **not** being considered. See 37 CFR 1.97(i).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the

description: reference signs 24a and 24b in Figures 3A and 3C. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 6, 9, and 15 are objected to because of the following informalities: In claim 6 at line 2, and in claim 9 at line 19, the quotation marks should be removed from the word "aggregate". In claim 15, at line 21, the quotation marks should be removed from the word "capture". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, at lines 2 and 8, the open and close parenthesis should be deleted so that it is clear that that the material surrounded by the parenthesis is part of the claim. The same applies to dependent claims 2-8.

In claim 1, at line 15, the terms "high" and "low" are relative terms. It is requested that said terms be changed to "relatively high" and "relatively low", respectively, so as to more clearly point out the invention. The same applies to dependent claims 2-8.

In claim 1, at each of lines 16 and 20, the term "predetermined" renders the claim indefinite because it is subjective. The same applies to dependent claims 2-21. In particular, said term appears in claim 5 at line 2 and in claim 6 at line 1. It is suggested that said term be deleted from all of the above locations in claims 1, 5, and 6.

In claim 1, at each of lines 19 and 23, the term "the capture immunoreagent" should be changed to "the at least one capture immunoreagent" so as to clearly point out which capture immunoreagent is being referred to. The same applies to dependent claims 2-8. In particular, in claim 6, at line 3, the term "the capture immunoreagent" should be changed to "the at least one capture immunoreagent".

In claim 9, at lines 2 and 6, the open and close parenthesis should be deleted so that it is clear that that the material surrounded by the parenthesis is part of the claim. The same applies to dependent claims 10-14.

In claim 9, at line 13, the terms "high" and "low" are relative terms. It is requested that said terms be changed to "relatively high" and "relatively low", respectively, so as to more clearly point out the invention. The same applies to dependent claims 10-14.

In claim 9, at each of lines 14 and 17, the term "predetermined" renders the claim indefinite because it is subjective. The same applies to dependent claims 10-14. It is suggested that said term be deleted.

In claim 13, at line 4, the term "the capture immunoreagent" should be changed to "the at least one capture immunoreagent" so as to clearly point out which capture immunoreagent is being referred to.

In claim 15, at lines 3 and 7, the open and close parenthesis should be deleted so that it is clear that that the material surrounded by the parenthesis is part of the claim. The same applies to dependent claims 2-8.

In claim 15, at line 13, the terms "high" and "low" are relative terms. It is requested that said terms be changed to "relatively high" and "relatively low", respectively, so as to more clearly point out the invention. The same applies to dependent claims 16-21.

In claim 15, at each of lines 14 and 18, the term "predetermined" renders the claim indefinite because it is subjective. The same applies to dependent claims 16-21. In particular, said term appears in claim 20, at line 2. It is suggested that said term be deleted from all of the above locations in claims 15 and 20.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cheng et al, U.S. Patent 6,071,394.

Cheng et al teaches a method for isolating and immobilizing cell particles of interest on an active electronic matrix chip device as here claimed (see Figures 1 and 2 as well as instant Figures 1 and 2; col. 7, line 6 through col. 8, line 35). In particular, there is a substrate, individually addressable electrodes (24) on the substrate, a permeation layer overlying the plurality of electrodes on the substrate, and, for example streptavidin, which is a capture immunoreagent specific for the bioparticle of interest (e.g., *E. coli* cells), attached to the permeation layer at the instant microlocations (see col. 7, line 6 through col. 8, line 35; col. 8, line 41 through col. 11, line 9). In Cheng et al's method, a sample solution containing the *E. coli* is introduced onto the device, wherein the solution is of a conductivity suitable for dielectrophoretic isolation of the *E. coli*; and alternating current is passed through the device and produces the instant areas of high and low alternating current field strength such that the *E. coli* cells collect at field maxima, and undesired cells collect at field minima (see col. 8, line 41 through col. 11, line 9; Figures 3A and 3B; and instant Figures 3A and 3B). Although not specifically stated, it is the Examiner's position that the *E. coli* is bound to the streptavidin. The permeation layer surface of the device is then washed so as to

remove the undesired cells (see col. 11, lines 10-19). In another example, HeLa cells are the bioparticle of interest, and the HeLa cells are detectably labeled with fluorescent stain (see col. 15, lines 9-26). The fluorescent dye used is a nucleic acid-binding fluorescent dye and is a detection immunoreagent (see col. 15, lines 9-13). A solution of said fluorescent dye is pumped into the flow cell containing the HeLa cells, and the staining (incubation) takes about 60 seconds (see col. 15, lines 9-16). The HeLa cells are then detected (imaged) (see col. 15, lines 14-16). The position where the *E. coli* or HeLa cells aggregate is, as noted above, at the filed maxima of the electrodes (24), and these maxima locations are the instant aggregate microlocations (see col. 10, lines 38-55; and col. 14, lines 50-54).

With respect to claims 7, 9 and 15 and their dependent claims, the aggregated *E. coli* cells are then lysed to release sub-cellular constituents, such as DNA (see col. 11, lines 20-31). An oligonucleotide capture probe is then immobilized on the microlocations containing the streptavidin, and a direct current of 200 nA is applied to each electrode so as to bind the DNA to the capture probe (see the paragraph bridging cols. 11 and 12). An oligonucleotide target (i.e., detection immunoreagent) is then introduced, and a direct current is maintained at 450 nA to bind the DNA to the oligonucleotide target, and thus provide a label on the DNA (see col. 12, lines 7-25). The oligonucleotide target is then "detected" is a sandwich assay (see col. 12, lines 26-37). In the sandwich assay, there is washing to remove undesirable components (see col. 12, lines 26-37).

Since Cheng et al teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

In addition, the presently claimed limitation that the capture immunoreagent binds to the particle of interest would obviously have been present when Cheng et al's *E. coli* cells or HeLa cells bind to the streptavidin. Note on page 22, line 29, of the instant specification that streptavidin is a capture immunoreagent. Note also In re Best, 195 USPQ at 433, footnote 4 (CCPA 1977) as to the providing of this rejection under 35 USC 103 in addition to the rejection made above under 35 USC 102.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,071,394. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a capture immunoreagent would have been within the skill of an artisan so as to collect the desired cells in the cell mixture (see

claim 20 of said patent). The checkerboard format in claim 20 of said patent inherently encompasses the use of the instant alternating current.

11. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,280,590. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a capture immunoreagent would have been within the skill of an artisan so as to collect the desired cellular materials (see claim 8 of said patent). The checkerboard format in claim 8 of said patent inherently encompasses the use of the instant alternating current.

12. Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/905,755. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a capture immunoreagent would have been within the skill of an artisan so as to collect the desired cellular materials (see claim 17 of said copending application). The checkerboard format in claim 17 of said copending application inherently encompasses the use of the instant alternating current.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2001/0045359 has published from Serial No. 09/905,755. Also made of record are 6,051,380, 6,245,508, 6,254,827, 6,518,022, 2003/0146145, 2004/0011650, and 6,726,880.

Also made of record is Yang et al, "An integrated stacked microlaboratory for biological agent detection with DNA and immunoassays," Biosensors and Bioelectronics, Vol. 17, pages 605-618, (2002).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan Diamond whose telephone number is 571-272-1338. The examiner can normally be reached on Monday through Friday, 5:30 a.m. to 2:00 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alan Diamond
Primary Examiner
Art Unit 1753

Alan Diamond
August 13, 2004